



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re Application of:**

Cox et al.

**Serial No.:** 10/539,672

**Filed:** June 14, 2005

**For:** MASTITIS TREATMENT

**Examiner:** S. Jean-Louis

**Group Art Unit:** 1627

**Attorney Docket No.:** 1963-9527US

NOTICE OF EXPRESS MAILING

Express Mail Mailing Label Number: EM417189902US

Date of Deposit with USPS: May 25, 2010

Person making Deposit: Grady C. Evans

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT  
UNDER 37 C.F.R § 1.705(b)**

Mail Stop Patent Ext.  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In response to the Notice of Allowance mailed on March 23, 2010 (hereinafter "Notice of Allowance"), the applicants submit the following request for reconsideration of patent term adjustment. This Request for Reconsideration of Patent Term Adjustment includes:

- (1) The fee set forth in 37 C.F.R. § 1.18(e); and
- (2) The Statement of the Facts Involved required by 37 C.F.R. § 1.705(b)(2).

05/27/2010 HVUONG2 00000078 10539672

01 FC:1455

200.00 0P

## **STATEMENT OF THE FACTS INVOLVED**

### **(i) The correct patent term adjustment and the bases under 37 C.F.R. § 1.702 for the adjustment**

The correct patent term adjustment if the issue fee is paid by the date that is three months after the mailing date of the Notice of Allowance and the patent issues on or before the date that is four months after the date the issue fee was paid and all outstanding requirements were satisfied is 602 days.

Under the recent decision of the Federal Circuit in Wyeth v. Kappos, 591 F.3d 1364 (Fed. Cir. 2010), periods of delay in the Office that lead to patent term extensions under 35 U.S.C. § 154(b)(1) do not “overlap,” such that the period of adjustment may be limited, unless the periods of delay occur at the same time. Id., 591 F.3d at 1369-70 (invalidating the Office’s interpretation of 35 U.S.C. § 154(b)(1)).

Pursuant to 37 C.F.R. § 1.702(a)(1), the term of a patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to mail at least one of a notification under 35 U.S.C. § 132, or a notice of allowance under 35 U.S.C. § 151, not later than fourteen months after the date on which the application was filed under 35 U.S.C. § 111(a) or fulfilled the requirements of 35 U.S.C. § 371 in an international application. The present application is a national phase entry of an international application, and the present application fulfilled the requirements of 35 U.S.C. § 371 on June 16, 2005. Notice of Acceptance of Application under 35 U.S.C. 371 and 37 CFR 1.495 of December 9, 2005. The first notification mailed by the Office under 35 U.S.C. § 132 in the present application was a Restriction Requirement mailed on October 2, 2007. Therefore, applicants are entitled to 412 days of patent term extension under 37 C.F.R. § 1.702(a)(1) in the present case, which is the period between August 16, 2006, and October 2, 2007.

Pursuant to 37 C.F.R. § 1.702(a)(2), the term of a patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to respond to a reply under 35 U.S.C. § 132 or to an appeal taken under 35 U.S.C. § 134 not later than four months after the date on which the reply was filed or the appeal was taken. A reply under 35 U.S.C. § 132 was entered in the present application on November 18, 2009. Amendment of November 18, 2009. A response to this reply, in the form of a Notice of Allowance, was mailed by the Office on March 23, 2010.

Therefore, applicants are entitled to 5 days of patent term extension under 37 C.F.R. § 1.702(a)(2) in the present case, which is the period between March 18, 2010, and March 23, 2010.

Pursuant to 37 C.F.R. § 1.702(b), the term of a patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the national stage commenced under 35 U.S.C. § 371(b) or (f) in an international application. The present application is a national phase entry of an international application, and the present application entered the national phase on June 14, 2005. Notice of Acceptance of Application under 35 U.S.C. 371 and 37 CFR 1.495 of December 9, 2005. A period of delay for purposes of 37 C.F.R. § 1.702(b) began on June 14, 2008. Applicants filed a Request for Continued Examination in the Office on May 27, 2009. Pursuant to 37 C.F.R. § 1.702(b)(1), the period of delay under 37 C.F.R. § 1.702(b) beginning on June 14, 2008, should not include the period after May 27, 2009. Therefore, applicants are entitled to the 346 days of patent term extension under 37 C.F.R. § 1.702(b) in the present case, which is the period between June 14, 2008, and May 27, 2009.

The 412 day period of delay under 37 C.F.R. § 1.702(a)(1) began on August 16, 2006, and ended on October 2, 2007. The 5 day period of delay under 37 C.F.R. § 1.702(a)(2) began on March 18, 2010, and ended on March 23, 2010. And, the 346 day period of delay under 37 C.F.R. § 1.702(b) began on June 14, 2008, and ended on May 27, 2009. Thus, none of these periods of delay overlap, such that the patent term extension could permissibly be restricted. Wyeth, 591 F.3d at 1369-70. The sum of these periods is 763 days.

The period of patent term adjustment should be reduced for several periods set forth in 37 C.F.R. § 1.704. First, the patent term adjustment should be reduced by 11 days, which corresponds to a period in excess of 3 months taken by the applicants to respond to the Non-final Office Action mailed on August 7, 2009 (Amendment under 37 C.F.R. § 1.111 entered on November 18, 2009). Second, the patent term adjustment should be reduced by 59 days, which corresponds to a period in excess of 3 months taken by the applicants to respond to the Non-final Office Action mailed on November 9, 2007 (Amendment under 37 C.F.R. § 1.111 entered on April 8, 2008). Lastly, the patent term adjustment should be reduced by 91 days, which corresponds to a period in excess of 3 months taken by the applicants to respond to the Final

Office Action mailed on July 9, 2008 (Notice of Appeal entered on January 8, 2009). Thus, the total amount of reduction to the patent term adjustment should be 161 days, which is the sum of the three periods set forth in 37 C.F.R. § 1.704, *supra*.

**(ii) The adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled and the relevant dates as specified in 37 C.F.R. §§ 1.703(a)-(e) for which the adjustment is sought**

The present patent is entitled to a patent term extension of 602 days under 37 C.F.R. § 1.703(f), as this number represents the sum of the periods of delay set forth in 37 C.F.R. §§ 1.703(a)-(e) (763 days), less the periods set forth in 37 C.F.R. § 1.704 (161 days).

The present patent is entitled to a patent term extension of 417 days under 37 C.F.R. § 1.703(a) (412 days under 37 C.F.R. § 1.703(a)(1) and 5 days under 37 C.F.R. § 1.703(a)(2)). The present patent is at least additionally entitled to a patent term extension of 346 days under 37 C.F.R. § 1.703(b). As set forth, *supra*, the 412 day period of delay under 37 C.F.R. § 1.702(a)(1) began on October 16, 2005, and ended on October 2, 2007; the 5 day period of delay under 37 C.F.R. § 1.702(a)(2) began on March 18, 2010, and ended on March 23, 2010; and, the 346 day period of delay under 37 C.F.R. § 1.702(b) began on June 14, 2008, and ended on May 27, 2009.

**(iii) Whether the patent is subject to a terminal disclaimer, and any expiration date specified in the terminal disclaimer**

Any patent issuing from the referenced patent application will not be subject to a terminal disclaimer.

**(iv) Any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704**

As described, *supra*, several circumstances set forth in 37 C.F.R. § 1.704 occurred during the prosecution of the referenced patent application. First, a period of 11 days in excess of 3 months was taken by the applicants to respond to the Non-final Office Action mailed on August 7, 2009 (Amendment under 37 C.F.R. § 1.111 entered on November 18, 2009). Second, a period

of 59 days in excess of 3 months was taken by the applicants to respond to the Non-final Office Action mailed on November 9, 2007 (Amendment under 37 C.F.R. § 1.111 entered on April 8, 2008). Lastly, a period of 91 days in excess of 3 months was taken by the applicants to respond to the Final Office Action mailed on July 9, 2008 (Notice of Appeal entered on January 8, 2009). The sum of the three periods is 161 days.

### CONCLUSION

Applicants respectfully request reconsideration of the Patent Term Adjustment, and modification of the Patent Term Adjustment to 602 days (763 days of delay under 37 C.F.R. §§ 1.703(a)-(e), less 161 days of delay under 37 C.F.R. § 1.704). Applicants reserve the right to file further petitions or requests seeking additional patent term adjustments; *e.g.*, patent term adjustments that cannot be calculated until the issue date of the patent is actually known.

Applicants do not believe that any other fee is due in connection with this filing. If, however, the applicants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. 02-2334. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. 1.16 or 1.17 in connection with the referenced patent application, the Commissioner is hereby authorized to charge such deficiency, or credit such overpayment, to Deposit Account No. 02-2334. If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number below.

Respectfully submitted,  
/William M. BLACKSTONE, Registration No. 29,772/

William M. Blackstone, Registration No. 29,772  
Office of General Counsel – Merck & Co., Inc.  
Intellectual Property – Animal Health  
Law Dept. K-6-1, 1990  
Schering – Plough Corporation  
2000 Galloping Hill Road  
Kenilworth, NJ 07033  
(tel) 410 464 0491

Date: May 24, 2010

Enclosures: Fee under 37 C.F.R. § 1.18(e)